K110779

510(k) Premarket Notification
Spacelabs Healthcare
Spacelabs Smart Disclosure System, Model 92810
510(k) Summary

APR 19 2011

Submission Date:	14 March 2011
Submitter:	Spacelabs Healthcare 5150 220th Avenue SE Issaquah, WA 98029
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Official Contact:	Thomas Kroenke Principal Consultant Speed To Market, Inc. PO Box 3018 Nederland, CO 80466 USA tkroenke@speedtomarket.net 303 956 4232
Manufacturing Site:	Spacelabs Healthcare 5150 220th Avenue SE Issaquah, WA 98029
Trade Name:	Spacelabs Smart Disclosure System, Model 92810
Common Name:	Computer, Diagnostic, Programmable
Classification Name:	Programmable Diagnostic Computer
Classification Regulation:	21 CFR §870.1425
Product Code:	DQK

Substantially Equivalent Devices:	*New Spacelabs Model*	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
	Spacelabs Smart Disclosure System, Model 92810	K063490	Spacelabs Medical Inc. / Full Disclosure System, Model 91810

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Device Description:

The Spacelabs Healthcare (Spacelabs) Smart Disclosure System (Smart Disclosure), Model 92810, is a software only medical device that resides on a server or a client workstation. It is an update to the predicate device, the Spacelabs Full Disclosure, Model 91810, cleared by FDA in 510(k) submission K063490. Smart Disclosure is presented as an icon that, when selected, opens Smart Disclosure on a client workstation.

Smart Disclosure allows the recall and retrospective review of up to 72 hours of electrocardiogram (ECG) and other physiological waveforms and alarm events that are stored in the Spacelabs Network Database. The clinician can review vital signs information which enhances the ability to evaluate a patient's history. Smart Disclosure is able to reproduce the waveform data and events on the client workstation graphic display as well as in printed reports. The clinician can review infrequent events and ensures that onsets and terminations of the events are captured, and make standard-sized tracings using a network-connected laser printer. Additionally, the clinician can perform a shape-based retrospective analysis of the ECG waveform data using the Smart Disclosure shape-based retrospective algorithm.

Intended Use:

The Spacelabs Smart Disclosure System, Model 92810 is indicated for use in clinical situations where there is a need for review of physiological waveform information and alarm events up to 72 hours after the fact. Smart Disclosure is also indicated in those situations where a retrospective analysis of monitoring patients' ECG waveform data, that can be annotated and edited, is desired.

The intended use of the Spacelabs Smart Disclosure is to interface with the Spacelabs monitoring network, providing the user with a means of recalling waveform information and performing retrospective analysis. The most recent 72 hours of monitored patient ECG waveform data can be analyzed, with each analysis limited to 24 hours or less.

Technology Comparison:

The Smart Disclosure employs the same technological characteristics as the predicate device.

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Summary of Performance Testing:

Performance Testing

The Smart Disclosure was tested for performance in accordance with internal requirements.

Test results indicated that the Smart Disclosure complies with its predetermined specification and with the applicable Standards.

Software Testing

Software device modifications made to the Smart Disclosure were designed and developed according to a robust software development process, and were rigorously verified and validated.

Software information is provided in accordance with:

- *FDA guidance: The content of premarket submissions for software contained in medical devices, 11 May 05;*
- *FDA guidance: Off-the-shelf software use in medical devices, 09 Sep 99; and*
- *FDA guidance: General principles of software validation; Final guidance for industry and FDA staff, 11 Jan 02.*

Test results indicate that the Smart Disclosure complies with its predetermined specification.

Conclusion

Verification and validation activities were conducted to establish the performance and safety characteristics of the software device modifications made to the Smart Disclosure. The results of these activities demonstrate that the Smart Disclosure is safe and effective when used in accordance with its intended use and labeling.

Therefore, the Smart Disclosure is considered substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Spacelabs Helathcare
c/o Mr. Thomas Kroenke
Speed to Market, Inc.
PO Box 3018
Nederland, CO 80466

APR 19 2011

Re: K110779
Trade Name: Spacelabs Smart Disclosure System, Model 92810
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: March 14, 2011
Received: March 21, 2011

Dear Mr. Kroenke:

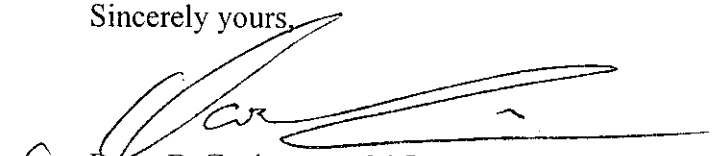
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 110779

Device Name: Spacelabs Smart Disclosure System, Model 92810

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
for Division of Cardiovascular Devices

510(k) Number K110779